

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia

Protocol summary

Study aim

To assess the safety and efficacy of Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia

Design

This is a non-randomized, interventional, single-group assignment study to assess the safety and feasibility of an allogeneic NK cell therapy on ten patients with high-risk acute myeloid leukemia who are candidates for allogeneic hematopoietic stem cell transplantation.

Settings and conduct

The study is a single-group clinical trial to evaluate the safety and efficacy of Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia at the Hematology-Oncology-Stem Cell Transplantation Research Center (HORCSCT) of Tehran University.

Participants/Inclusion and exclusion criteria

Patients over and equal to 18 years of age with high-risk acute myeloid leukemia who are candidates for allogeneic hematopoietic stem cell transplantation from matched or mismatched donors are included in the study. Patients with uncontrolled infection or severe acute graft-versus-host disease are excluded from the study

Intervention groups

All patients will be assigned to the only interventional arm of the study. Recipients of allogeneic Stem Cell Transplantation will receive the systemic intravenous infusion of natural killer cells at days +6 and +12 post-transplantation.

Main outcome variables

Natural Killer cell infusion-related Adverse Events, Relapse incidence for one year after infusion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N35**

Registration date: **2023-07-13, 1402/04/22**

Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**

Update count: **0**

Registration date

2023-07-13, 1402/04/22

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 3691

Email address

ctu@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia

Public title

Natural Killer cell in acute myeloid leukemia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 years old or more Recipients of allogeneic Stem Cell Transplantation for high-risk Acute Myeloid Leukemia by ELN classification Recipients of allogeneic Stem Cell Transplantation from matched or mismatched donors. MRD $\geq$ 5% after the first Induction or MRD $\geq$ 0.1% after the second Induction or MRD $\geq$ 0.01% before transplantation Normal organ function

Exclusion criteria:

Second allogeneic Stem Cell Transplantation Active or uncontrolled infection Acute graft versus host disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran Univer

Street address

Kargar shomali Ave., Shariati hospital

City

Tehran

Province

Tehran

Postal code

1411713131

Approval date

2022-08-11, 1401/05/20

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1401.011

Health conditions studied**1****Description of health condition studied**

acute myeloid leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes**1****Description**

Number of Patients With Grades 3-5 of Natural Killer cell infusion-related Adverse Events

Timepoint

Daily during the first seven days after the injection

Method of measurement

History, Physical exam, and lab test

2**Description**

Relapse Incidence

Timepoint

one year after infusion

Method of measurement

Bone marrow aspiration and biopsy

Secondary outcomes

empty

Intervention groups**1****Description**

All patients are included in the only intervention arm of the study. Patients in the intervention arm will receive two doses of in-vitro expanded NK cells at the 6 and 12 days after transplantation under full supervision and in an isolated room. The process of isolation and preparation of NK cells will be done in a clean room with clinical grade and suitable conditions for producing NK cells. 20 to 30 cc of peripheral blood was taken from the third-party donor and after the isolation of mononuclear cells, CD56+/CD3- reproduced. A viability test is done using trypan blue and phenotyping is used to check the absolute number and purity of cells.

Category

Treatment - Drugs

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers1**Recruitment center****Name of recruitment center**Hematology- Oncology and Stem Cell Transplantation
Research Center, Tehran University of Medical Sci**Full name of responsible person**

Maryam Barkhordar

Street address

North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1417713135

Phone

+98 21 8800 4140

Email

barkhordarm.n@gmail.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Ahmadvand

Street address

Kargar-e-Shomali Ave.

City

Tehran

Province

Tehran

Postal code

1411713131

Phone

+98 913 185 6733

Email

ahmadvand.mohamad64@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Barkhordar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Kargar-e-Shomali Ave.

City

Tehran

Province

Tehran

Postal code

1411713131

Phone

+98 21 8800 4140

Email

barkhordarm.n@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Vaezi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Kargar-e-Shomali Ave.

City

Tehran

Province

Tehran

Postal code

1411713131

Phone

+98 21 8800 4140

Email

vaezi.mohammad@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Barkhordar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Kargar-e-Shomali Ave.

City

Tehran

Province

Tehran

Postal code

1411713131

Phone

+98 21 8800 4140

Email

barkhordarm.n@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available